

REMARKS

Claims 1, 3-27 and 46, and 48-71 are pending herein. By the Office Action, claims 18-27 and 46-58 are withdrawn from consideration; claims 1, 5-6, 8-11, 14, 17 and 68-72 are rejected under 35 U.S.C. §102; and claims 1-17 and 59-72 are rejected under 35 U.S.C. §103. By this Amendment, claims 2, 47, and 72 are canceled and claims 1, 3-5, and 48-49 are amended. No new matter is added.

I. Information Disclosure Statements

A. February 6, 2002

An Information Disclosure Statement with Form PTO-1449 was filed on February 6, 2002. Although the Office Action enclosed an initialed copy of the Form PTO-1449, the non-patent reference was not initialed to acknowledge the fact that the Examiner has considered the cited information. The Examiner is requested to initial and return to the undersigned a copy of the subject Forms PTO-1449. For the convenience of the Examiner, a copy of those forms is attached.

B. September 17, 2003

An Information Disclosure Statement with Form PTO-1449 was filed on September 17, 2003. The Examiner is requested to initial and return to the undersigned a copy of the subject Forms PTO-1449.

II. Restriction Requirement

Claims 18-27 and 46-58 are withdrawn from consideration as subject to a Restriction Requirement. Applicants respectfully traverse the Restriction Requirement.

The Restriction Requirement is traversed because the claims of Groups I and II are drawn to sufficiently inter-related inventions to warrant examination thereof in a single application. Group I is drawn to compositions, particularly biocompatible adhesive compositions. Group II is drawn to methods of treating tissue using such compositions.

Where product and process claims are presented in the same application, Applicant may be called upon under 35 U.S.C. §121 to elect claims to either the product or process. MPEP §821.04. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Id. This policy should apply to Groups I and II.

In the present application, the method claims of Group II include all of the limitations of the product of Group I. In particular, all of the limitations of the independent product claim 1 of Group I are incorporated into the method claims of Group II.

Since the method claims of Group II include the limitations of the product claims of Group I, the method claims must be rejoined with the product claims once the product claims are allowed. Thus, to streamline prosecution and avoid delay, the Restriction Requirement should be withdrawn to permit concurrent examination of all of the pending claims. Applicant respectfully requests reconsideration and withdrawal of the Restriction Requirement.

The Restriction Requirement is also traversed because the subject matter of Groups I and II is sufficiently related that a search of any one group would encompass a search of the subject matter of the remaining group. The prior art revealed by a search of the biocompatible adhesive compositions of Group I would overlap the prior art revealed by a search of the method of treating tissue using such compositions. Thus, although the classifications may be different, the subject matter is sufficiently overlapping that concurrent search of all of the claims does not create a serious burden.

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent claims. MPEP §803. Applicant respectfully submits that there would be no serious burden on the Patent Office to examine all of the present claims because the subject

matter of Groups I and II is sufficiently related that a search of any one group would encompass the search of the subject matter of the remaining groups. Thus, the Restriction Requirement is improper and should be withdrawn.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the Restriction Requirement.

III. Rejection Over Berger

Claims 1, 8-11, 14, 17 and 68-71 are rejected under 35 U.S.C. §102(e), or alternatively under 35 U.S.C. §103(a), over Berger. The Office Action argues that Berger discloses, or at least would have rendered obvious, all of the limitations of the claimed invention.

Although Applicants do not necessarily agree with the rejections, in the interest of advancing prosecution claim 1 is amended to incorporate the limitations of non-rejected claim 2. Accordingly, the rejections are overcome and should be withdrawn.

IV. Rejection Over Akimova or EP 252

Claims 1, 5-6, 8-11, 14, 17, 68-69 and 72 are rejected under 35 U.S.C. §102(b), or alternatively under 35 U.S.C. §103(a), over Akimova or EP 252. The Office Action argues that Akimova or EP 252 discloses, or at least would have rendered obvious, all of the limitations of the claimed invention.

Although Applicants do not necessarily agree with the rejections, in the interest of advancing prosecution claim 1 is amended to incorporate the limitations of non-rejected claim 2. Accordingly, the rejections are overcome and should be withdrawn.

V. Rejections Over Clark

A. Clark in view of Banitt, Collins, EP 623 and Harwood

Claims 1, 5-11, 14, 17 and 68 are rejected under 35 U.S.C. §103(a) over Clark in view of Banitt, Collins, EP 623 and Hammerslag. The Office Action argues that the claimed

invention would have been obvious over the cited references. Applicants respectfully traverse this rejection.

Although Applicants do not necessarily agree with the rejections, in the interest of advancing prosecution claim 1 is amended to incorporate the limitations of non-rejected claim 2. Accordingly, the rejections are overcome and should be withdrawn.

B. Clark in view of Kronenthal, Collins, EP 623 and Harwood

Claims 1-4, 8-17 and 59-68 are rejected under 35 U.S.C. §103(a) over Clark in view of Kronenthal, Collins, EP 623 and Hammerslag. The Office Action argues that the claimed invention would have been obvious over the cited references. Applicants respectfully traverse this rejection.

1. The Claimed Invention

The claimed invention is generally directed to biocompatible adhesive compositions, methods of treating tissue using such compositions, and kits containing such compositions. In particular, claim 1 is directed to a biocompatible adhesive composition, comprising: a first monomer species; and a second monomer species different from said first monomer species, wherein at least said first monomer species is absorbable, an absorption rate of said first monomer species is different from an absorption rate of said second monomer species, and wherein said first monomer species comprises an alkyl ester cyanoacrylate. Independent claim 59 is directed to a biocompatible adhesive composition, comprising: at least one alkyl ester cyanoacrylate monomer; a second monomer species having an absorption rate different from an absorption rate of said at least one alkyl ester cyanoacrylate monomer; and a polymerization initiator or accelerator, wherein said polymerization initiator or accelerator is a quaternary amine.

Thus, as pending, each of independent claims 1 and 59 specifically requires the presence of an alkyl ester cyanoacrylate as the first monomer species. Such compositions are nowhere taught or suggested in Clark.

2. Clark Does Not Teach or Suggest the Claimed Invention

Clark is directed to an applicator tip for dispensing a polymerizable and/or cross-linkable material which is porous, absorbent or adsorbent and includes a polymerization or cross-linking initiator. The initiator initiates polymerization or cross-linking when the polymerizable and/or cross-linkable material is dispensed through the applicator tip. The polymerizable and/or cross-linkable material may be applied to a variety of substrates. See Clark at Abstract.

The Office Action correctly points out that Clark discloses the use of various cyanoacrylate monomers. However, Clark nowhere specifically discloses, and entirely fails to teach or suggest, the use of alkyl ester cyanoacrylates, as specifically required by the claimed invention, in combination with a second, different monomer species that has an absorption rate that is different from the alkyl ester cyanoacrylate. Clark specifically discloses a number of suitable monomers, including specific suitable cyanoacrylate monomers, but fails to disclose the specific alkyl ester cyanoacrylates from within the generic group of cyanoacrylates. Still further, Clark nowhere teaches or suggests that any such specifically selected cyanoacrylate monomer should specifically be used in combination with a second, different monomer species, as claimed. Clark entirely fails to disclose the combined use of the two different monomer species, as claimed.

With respect to the monomers, Clark discloses that the monomers may suitably be selected from 1,1-disubstituted monomers of the formula $\text{CHR}=\text{CXY}$. See col. 4, lines 35-44. Clark goes on to disclose that preferred and "especially advantageous" monomers are the cyanoacrylates, including those of formula (II). See col. 4, line 52 to col. 5, line 12. At

most, the disclosure of Clark only broadly encompasses the alkyl ester cyanoacrylates, if the substituents R^3 , R^7 and R^8 are properly selected. Clark also discloses preferred monomers to include alkyl alpha-cyanoacrylates, such as 2-octyl cyanoacrylate. Col. 5, lines 33-39.

However, Clark does not disclose, teach or suggest specific examples of the alkyl ester cyanoacrylates. Nor does Clark disclose, teach or suggest the combined use of two or more monomer species, having different absorption rates, in any combination, much less in the combination required by the present independent claims. Clark does not teach or suggest any preference for one monomer over the rest, except perhaps for the use of alkyl alpha cyanoacrylates, and by no means discloses or suggests any preference for alkyl ester cyanoacrylates, which are not specifically disclosed in the reference.

Although the disclosure of Clark may broadly encompass the various specific monomer components of the claimed invention individually, Clark would not have rendered obvious the claimed invention. In particular, Clark does not teach or suggest any preference for one monomer over the rest, does not teach or suggest the specific alkyl ester cyanoacrylates, and does not teach or suggest the use of two different monomer species having different absorption rates, as claimed. In the present case, Clark fails to teach or suggest specifically selecting the alkyl ester cyanoacrylate monomer and a second, different monomer having a different absorption rate, as claimed. Clark only broadly encompasses the use of alkyl ester cyanoacrylates or other cyanoacrylate monomers. In the absence of any such teachings, the reference cannot have rendered obvious the claimed invention.

3. The Secondary References Fail to Overcome Clark's Deficiencies

Furthermore, none of the secondary references, alone or in combination, overcome the above-described deficiencies of Clark, whether alone or in combination.

Kronenthal is cited for its disclosure of carbalkoxyalkyl 2-cyanoacrylates, which are disclosed to be readily assimilated by tissues and exhibit a relatively low degree of

inflammatory tissue response. However, Kronenthal fails to disclose, teach or suggest that one of ordinary skill in the art should select two different monomer species, each having different absorption rates, for use in a biocompatible adhesive composition, as claimed. At most, one of ordinary skill in the art might have been motivated to modify Clark by using only the carbalkoxyalkyl 2-cyanoacrylate of Kronenthal. However, such a modification still would not have yielded the claimed invention.

Collins is cited for its disclosure that octyl 2-cyanoacrylate is a more effective tissue adhesive. Collins is further cited for its alleged teaching that a composition is desired having the low toxicity and fast polymerization rate of the higher homolog cyanoacrylates, and the biodegradability of methyl cyanoacrylate. However, Collins likewise fails to disclose, teach or suggest that one of ordinary skill in the art should select two different monomer species, each having different absorption rates, for use in a biocompatible adhesive composition, as claimed. In fact, when considered in combination with Clark and Kronenthal, Clark and Collins appear to be directly contradictory to Kronenthal. Each of Clark and Collins express a distinct preference for alkyl alpha-cyanoacrylates, whereas Kronenthal expresses a preference for carbalkoxyalkyl 2-cyanoacrylate. Accordingly, one of ordinary skill in the art would at best have been motivated to use either the monomers of Clark and/or Collins, or the monomers of Kronenthal, but not a combination of them. Any combination of the references thus would still not have provided the claimed invention.

EP 623 is cited for its disclosure of stabilizing agents. Hammerslag is cited for its disclosure that different monomers biodegrade at different rates. However, neither of these references overcomes the above-described deficiencies of the primary references.

4. Conclusion

Accordingly, considering the cited references in combination, one of ordinary skill in the art would not have been motivated to practice the claimed invention. The cited references fail

to teach or suggest selecting a plurality of different monomer species, having different absorption rates, where the first monomer species is an alkyl ester cyanoacrylate as claimed.

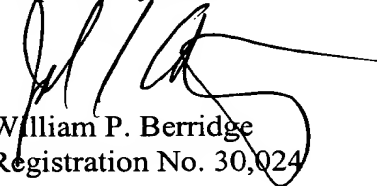
The claimed invention is thus patentable over the cited references. Reconsideration and withdrawal of the rejection are respectfully requested.

VI. Conclusion

In view of the foregoing amendments and remarks, Applicants submit that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,



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WPB:JSA

Attachment:
Form PTO-1449

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